UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

IN RE ZETIA (EZETIMIBE) ANTITRUST LITIGATION This document relates to: All Actions	MDL No. 2:18-md-2836

PURCHASERS' RESPONSE TO DEFENDANTS' OBJECTIONS TO REPORT AND RECOMMENDATION ON DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

I. INTRODUCTION 1

II. LEGAL STANDARD 1

III. ARGUMENT 2

A. The R&R correctly concludes genuine issues of material fact exist as to whether Merck made a "large and unjustified" payment 2

1. The R&R correctly considers all the purchasers' evidence of the no-AG agreement. 3

2. The purchasers appropriately valued the no-AG agreement. 6

3. Merck's $9 million payment to Glenmark to reimburse incurred litigation costs is part of the "large and unjustified" payment. 8

B. The R&R correctly recognizes the anticompetitive effect of Merck's no-AG agreement to be disputed. 8

1. The R&R is not based on a theory of anticompetitive harm that the purchasers abandoned. 9

2. The R&R correctly concludes that the purchasers' evidence is sufficient to support a conclusion that Merck paid Glenmark to avoid the risk of competition. 13

3. The R&R correctly rejects the argument that *Actavis* requires a reverse payment to eliminate the risk of competition from every would-be generic. 15

C. The R&R correctly recognizes a genuine dispute of fact as to the purchasers' causation theory. 19

1. The R&R correctly declines to recommend granting summary judgment on causation theories the purchasers are not pursuing. 19

2. The R&R correctly finds there is sufficient evidence of causation to withstand summary judgment. 20

3. The R&R correctly concludes that there is a material dispute about whether Glenmark had the manufacturing capacity to launch earlier. 25

4. The purchasers have created a genuine question of fact on antitrust injury. 28

IV. CONCLUSION 30

TABLE OF AUTHORITIES

Page(s)

Cases

In re AndroGel Antitrust Litig. (No. II),
No. 09-md-2084, 2018 WL 2984873 (N.D. Ga. June 14, 2018) 11, 12, 22, 29

Brunswick Corp. v. Pueblo Bowl-O–Mat, Inc.,
429 U.S. 477 (1977).....28

Celotex Corp. v. Catrett,
477 U.S. 317 (1986).....2

Conway v. 287 Corp. Ctr. Assocs.,
901 A.2d 341 (N.J. 2006).....5

Dash v. Mayweather,
731 F.3d 303 (4th Cir. 2013) 27

Dulaney v. Packaging Corp. of Am.,
673 F.3d 323 (4th Cir. 2012) 2

FTC v. Actavis,
570 U.S. 136 (2013)..... *passim*

In re Glumetza Antitrust Litig.,
No. 19-cv-5822, 2020 WL 4732333 (N.D. Cal. Aug. 15, 2020) 21

J. Truett Payne Co., Inc. v. Chrysler Motors Corp.,
451 U.S. 557 (1981).....21

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.,
791 F.3d 388 (3d Cir. 2015).....10, 11

King Drug Co. of Florence v. Cephalon, Inc.,
88 F. Supp. 3d 402 (E.D. Pa. 2015) 16

Lightfoot v. Georgia-Pacific Wood Prods., LLC,
No. 16-cv-244, 2018 WL 6729636 (E.D.N.C. Dec. 21, 2018).....7

In re Loestrin 24 Fe Antitrust Litig.,
433 F. Supp. 3d 274 (D.R.I. 2019).....17

In re Mid-Atl. Toyota Antitrust Litig.,
560 F. Supp. 760 (D. Md. 1983) 29

In re Modafinil Antitrust Litig.,
837 F.3d 238 (3d Cir. 2016).....16, 17

In re Namenda Direct Purchaser Antitrust Litig.,
331 F. Supp. 3d 152 (S.D.N.Y. 2018).....22, 29

In re Nexium (Esomeprazole) Antitrust Litig.,
842 F.3d 34 (1st Cir. 2016).....17

In re Opana ER Antitrust Litig.,
162 F. Supp. 3d 704 (N.D. Ill. 2016).....11

Reeves v. Sanderson Plumbing Prods., Inc.,
530 U.S. 133 (2000).....2

Sakaria v. Trans World Airlines,
8 F.3d 164 (4th Cir. 1993).....23, 27

In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.,
No. 14-md-02503, 2018 WL 563144 (D. Mass. Jan. 25, 2018).....11, 20, 21, 22

Ugbo v. All. Legal Grp., P.L.L.C.,
No. 15-cv-151, 2016 WL 9776593 (E.D. Va. Oct. 26, 2016).....2

United Food & Commercial Workers Loc. 1776 v. Teikoku Pharma USA,
296 F. Supp. 3d 1142 (N.D. Cal. 2017).....21, 22

Univac Dental Co. v. Dentsply Int'l, Inc.,
No. 07-cv-493, 2010 WL 1816745 (M.D. Pa. Apr. 27, 2010).....21

VS Techs., LLC v. Twitter, Inc.,
No. 11-43, 2011 WL 4744572 (E.D. Va. Oct. 5, 2011).....27

Wash. Cty. Health Care Auth., Inc. v. Baxter Int'l Inc.,
328 F. Supp. 3d 824 (N.D. Ill. 2018).....29

In re Wellbutrin XL Antitrust Litig.,
133 F. Supp. 3d 734 (E.D. Pa. 2015).....22

In re Wellbutrin XL Antitrust Litig.,
868 F.3d 132 (3d Cir. 2017).....16, 23

Statutes

21 U.S.C. § 505.....16

28 U.S.C. § 636.....1, 2

Other Authorities

Fed. R. Civ. P. 56 ..... 2, 19

Fed. R. Civ. P. 72 ..... 1, 2

Herbert Hovenkamp, et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (3d ed. 2017) 17

Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (4th ed. 2019) 12

I. INTRODUCTION

Magistrate Judge Miller carefully considers and ultimately rejects every one of the defendants' arguments for summary judgment in his comprehensive, seventy-four-page Report and Recommendation.[1] The defendants now reassert virtually every one of their summary judgment arguments as claimed errors in the R&R. The defendants continue to insist that there is no evidence that Merck made a no-AG promise to Glenmark, that the purchasers cannot establish any anticompetitive effects from the no-AG agreement, and that the purchasers cannot establish that the no-AG agreement caused any antitrust injury or damages. The R&R does not err in finding substantial disputes of material fact with respect to each these issues; they must be resolved at trial.

This case has been pending for five years. In that time, the purchasers have faced multiple rounds of Rule 12 practice, years of hard-fought discovery, delays caused by the COVID-19 pandemic, a trip to the Fourth Circuit and subsequent joinder proceedings, and the defendants' attempts to disqualify nearly every expert the purchasers offered. It is time for a jury to decide the remaining disputes. The defendants' objections should be overruled, and the R&R adopted.

II. LEGAL STANDARD

When reviewing a magistrate judge's report and recommendation, a district court must make a *de novo* determination about those portions of a report and recommendation to which objections are made.[2] A district court may accept, reject, or modify, in whole or in part, the

[1] R&R on Defs.' Mots. for Summ. J., ECF No. 1717 ("R&R").

[2] Fed. R. Civ. P. 72(b)(3); 28 U.S.C. § 636(b)(1)(C).

findings and recommendations made by a magistrate judge.[3]

Summary judgment is appropriate only where there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[4] In other words, such relief may only be granted if, "after reviewing the record as a whole," the Court determines no "reasonable jury could return a verdict for the" non-moving party.[5] The moving party must cite "particular parts of materials in the record" to establish that a material fact is undisputed.[6] "[A]ll reasonable inferences" must be drawn in favor of the non-moving party, and the Court "may not make credibility determinations or weigh the evidence."[7]

III. ARGUMENT

A. The R&R correctly concludes genuine issues of material fact exist as to whether Merck made a "large and unjustified" payment.

The R&R correctly concludes that the purchasers have established disputes of material fact regarding whether Glenmark agreed to delay its introduction of generic Zetia in return for Merck's agreement not to sell an authorized generic (a "no-AG agreement").[8] The defendants object to this conclusion as contrary to the four corners of a written settlement document. But as the R&R recognizes, the purchasers identified "extensive evidence that Glenmark sought a no-AG agreement during negotiations, and that both Merck and Glenmark made post-settlement decisions reflecting Defendants' mutual understanding that the settlement restricted Merck's

[3] Fed. R. Civ. P. 72(b)(3); 28 U.S.C. § 636(b)(1)(C).

[4] Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986).

[5] *Dulaney v. Packaging Corp. of Am.*, 673 F.3d 323, 330 (4th Cir. 2012).

[6] *Ugbo v. All. Legal Grp., P.L.L.C.*, No. 15-cv-151, 2016 WL 9776593, at *1 (E.D. Va. Oct. 26, 2016) (quoting Fed. R. Civ. P. 56(c)(1)).

[7] *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

[8] R&R at 30.

ability to launch an AG."[9] As Magistrate Judge Miller noted during oral argument, "there is clearly a ton of evidence that Merck knew it could not compete with Glenmark and that Glenmark was going to vigorously defend its ability to have exclusive rights to generic Ezetimibe during exclusivity."[10] Because the R&R is certainly correct that "[a] reasonable juror could rely on this evidence of the Agreement's restrictions on generic competition and Plaintiffs' other evidence to find that the provisions in question constitute a no-AG agreement,"[11] the defendants' only argument is that all of purchasers' evidence is legally irrelevant. But the R&R also considers that argument and properly rejects it.

1. The R&R correctly considers all the purchasers' evidence of the no-AG agreement.

This is an antitrust case, not a breach of contract case governed by the parol evidence rule. The issue is the totality of the evidence permits a jury to conclude Merck agreed to a no-AG commitment. The R&R correctly recognizes that this inquiry is not generally confined to the four corners of a written agreement because "'aspiring monopolists' are probably not 'foolish enough to reduce their entire anticompetitive agreement to writing,' but would instead draft a contract without the illegal terms."[12]

The defendants spend considerable effort trying to distinguish *Wholesale Grocery* claiming, "there is no *direct* evidence of any agreement outside the written settlement agreement" and that "the only alleged agreement is the written one,"[13] but that is not the case. As

[9] R&R at 31.

[10] Tr. of Aug. 17, 2022 Hr'g on Defs.' Mots. for Summ. J. at 35:4–8 ("Hr'g Tr.").

[11] R&R at 31.

[12] *Id.* at 32 (quoting *In re Wholesale Grocery Prods. Antitrust Litig.*, 752 F.3d 728, 734 (8th Cir. 2014)).

[13] Defs.' Objs. to R&R on Defs.' Mot. for Summ. J. at 8, ECF No. 1732 ("Defs.' Objs.").

Magistrate Judge Miller recognizes, the "drafting history suggests the parties intended to disguise the restriction on AG competition by recasting the defined term 'Authorized Generic' as a component of 'Generic Ezetimibe' and providing Glenmark with an exclusive license over both."[14] Substantial evidence also shows that "both Merck and Glenmark made post-settlement decisions reflecting Defendants' mutual understanding that the settlement restricted Merck's ability to launch an AG."[15] This is exactly the type of evidence that *Wholesale Grocery* contemplates.

Even under New Jersey contract law, chosen by the defendants in their written agreement, the R&R correctly concludes that extrinsic evidence should be considered. The R&R observes that under New Jersey law "ambiguous contractual terms permit the 'broad use of extrinsic evidence to achieve the ultimate goal of discovering the intent of the parties.'"[16] The defendants claim no extrinsic evidence should be considered because the written document is unambiguous.[17] But, contrary to the defendants' argument, the Court did not find the written settlement agreement to be unambiguous in ruling on the defendants' motion to dismiss. At that time, it recognized that "the Settlement Agreement did not allow Merck to sell a generic product, including an AG,"[18] and that the definition of "generic ezetimibe" in the settlement '"can plausibly be read as a no-AG agreement.'"[19] Thus, as the R&R explains, "the Settlement Agreement language is not so clear that summary judgment could be awarded to either party

[14] R&R at 33.

[15] R&R at 31 (citing Purchasers' Consol. Opp'n to Merck & Glenmark Defs.' Mots. for Summ. J. at 49–61, ECF No. 1155 ("Purchasers' Opp'n")).

[16] R&R at 31 (citing *Conway v. 287 Corp. Ctr. Assocs.*, 901 A.2d 341, 347 (N.J. 2006)).

[17] Defs.' Objs. at 6.

[18] Op. on Defs.' Mots. to Dismiss Pls.' Compls. at 20, ECF No. 489 ("Mot. Dismiss Op.").

[19] *Id.*

based on the textual argument alone."[20]

And, when ambiguity exists, New Jersey law takes an expansive view of parol evidence and "consider[s] all of the relevant evidence that will assist in determining the *intent and meaning* of the contract."[21] The New Jersey Supreme Court instructs that evidence:

> may "include consideration of the particular contractual provision, an overview of all the terms, the circumstances leading up to the formation of the contract, custom, usage, and the interpretation placed on the disputed provision by the parties' conduct." "Semantics cannot be allowed to twist and distort [the words'] obvious meaning in the minds of the parties." Consequently, the words of the contract alone will not always control.[22]

The R&R follows this law and explains, "ambiguous contractual terms permit the 'broad use of extrinsic evidence to achieve the ultimate goal of discovering the intent of the parties.'"[23]

The defendants' argument that the R&R does not "offer[] any explanation of how the language of the settlement agreement can be read to prohibit Merck from launching a branded authorized generic version of Zetia" is plainly incorrect.[24] But the R&R does so,[25] as did this Court in its Rule 12(b)(6) decision.[26] Magistrate Judge Miller found ample evidence that the language of the settlement agreement was ambiguous, and thus turned to extrinsic evidence to find Glenmark and Merck's actual intent.

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[20] R&R at 32.

[21] *Conway*, 901 A.2d at 346 (emphasis added).

[22] *Id.* at 347 (citations omitted) (quoting *Kearny PBA Local No. 21 v. Town of Kearny*, 405 A.2d 393, 400 (N.J. 1979); *Atl. N. Airlines v. Schwimmer*, 96 A.2d 652, 658 (N.J. 1953)).

[23] R&R at 31 (citing *Conway*, 901 A.2d at 347).

[24] Defs.' Objs. at 6–7.

[25] R&R at 31.

[26] Mot. Dismiss Op. at 21.

2. The purchasers appropriately valued the no-AG agreement.

The defendants also claim that the purchasers failed to properly value the no-AG agreement because those experts did not adopt the defendants' theory that the settlement agreement allows for the potential of a "second branded" ezetimibe product. But Magistrate Judge Miller correctly rejects this argument.

First, as the R&R recognizes, the purchasers identified evidence that the right to sell a second branded ezetimibe (even if such a right was intended by the parties) has no value. As Magistrate Judge Miller explains, the purchasers put forth evidence that brand manufacturers have never launched what the defendants call a "branded AG."[27] And Zetia does not fit into the category (oral contraceptives) where branded generics are occasionally launched.[28] The purchasers also cited evidence that there is no sound economic reason for Merck or any other brand manufacturer to ever launch any kind of second brand product to compete for generic sales.[29] The R&R further points to Merck's history of launching AGs. It never launched a "branded AG" like the product that Merck contends it specifically reserved the right to launch here, routinely launched traditional (unbranded) AGs for "every one of its blockbuster drugs that lost patent exclusivity between 2006 and 2017 except for Zetia," and "never sold a second branded product to compete with generics after losing exclusivity."[30] As the R&R explains, this evidence is not "immaterial" but is probative of how Merck and Glenmark valued the purported

[27] R&R at 36.

[28] *Id.*

[29] *Id.* at 36–37 (citing Dep. Of Meredith Rosenthal, Ph.D., ECF No. 1154-4 at 187:1–13); *see also* Mem. Order at 3,10–12, 14, 16–17, 19–20, 22, 23, 25, ECF No. 1314 (noting that Mr. Molina referred to this tactic as launching a "second brand").

[30] *Id.* at 37.

carveout for a second branded ezetimibe product.[31]

Magistrate Judge Miller did not err in concluding that the purchasers did not need to adjust the value of the no-AG provision to account for the defendants' argument that Merck reserved the right to sell a second branded product. The purchasers' evidence shows that such a carveout was essentially valueless because a second brand ezetimibe product "is not something that a brand company would consider marketing, and the evidence strongly suggests that Merck would not have done so."[32] The purchasers did not fail to value the alleged carveout. They essentially assigned it a value of $0.

Second, as the R&R correctly concludes, the purchasers were not required to value the no-AG agreement in accordance with defendants' self-serving *ex-post* interpretation of the provision. The purchasers amply supported their interpretation of the facts with citations to the record.[33] The purchasers' experts valued the no-AG provision consistently with that version of the facts, and, at summary judgment, the purchasers' "case does not fail just because they have not provided a different valuation that comports with Defendants' version of the facts."[34] In fact, the no-AG provision was valuable to both Merck and Glenmark. As Magistrate Judge Miller notes, the purchasers' experts estimated that Merck sacrificed between $25.5 million and $160

[31] *Id.*

[32] *Id.* at 35 (citing Purchasers' Opp'n at 51, ECF No. 1155).

[33] *Id.* at 42 (citing Mem. Op. and Order at 17–20, ECF No. 1649 ("McGuire and Leffler Order")); *see also Lightfoot v. Georgia-Pacific Wood Prods., LLC*, No. 16-cv-244, 2018 WL 6729636, at *2 (E.D.N.C. Dec. 21, 2018) (holding a court "should not disregard plaintiff's version of disputed facts when considering reliability and fit of an expert opinion under *Daubert*").

[34] R&R at 43.

million and Glenmark gained between $62.3 million and $125 million.[35] Because the purchasers provided a valuation of the no-AG provision consistent with the purchasers' version of disputed facts, summary judgment on this point is not appropriate.

3. Merck's $9 million payment to Glenmark to reimburse incurred litigation costs is part of the "large and unjustified" payment.

The R&R correctly finds that "as part of a reverse payment settlement the whole payment must be considered together."[36] The defendants seek to sever Merck's $9 million cash payment to Glenmark from the rest of the large and unjustified payment to try to force it into what they refer to as the FTC's "safe harbor" for traditional settlement considerations, such as avoided litigation costs. But the purchasers are not required to separately evaluate the $9 million payment as the defendants demand. Because "the $9 million moved from Merck the patent holder, to Glenmark, the alleged infringer, reasonable jurors could find it was part of a reverse payment, even if it partly or entirely reimbursed for expenses Glenmark had already incurred."[37] This is a correct statement of the law, and the defendants' objection should be overruled.

B. The R&R correctly recognizes the anticompetitive effect of Merck's no-AG agreement to be disputed.

In *Actavis*, the Supreme Court held that the "relevant anticompetitive harm" of an unexplained large reverse payment is that it "likely seeks to prevent the *risk* of competition."[38] The defendants argued that, even if the purchasers could prove that Merck made a reverse payment to Glenmark in the form of the no-AG provision, the purchasers could not prove that

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[35] *Id.* at 41, 42 (citing McGuire Report at 58–59, ECF No. 1079-81; Leffler Report at 47, ECF No. 1079-89).

[36] R&R at 46 (citing *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 418 (E.D. Pa. 2015)).

[37] R&R at 47.

[38] *FTC v. Actavis*, 570 U.S. 136, 157 (2013) (emphasis added).

the no-AG provision had any anticompetitive effect because: (1) they could not show that the no-AG provision was offered as a quid pro quo to avoid the risk of the litigation; and (2) Merck's reverse payment settlement with Glenmark did not avoid all risk of competition because Merck continued to face the potential invalidation of its patent from another generic company, Mylan. The defendants reassert these arguments and add that Magistrate Judge Miller incorrectly relied on a theory of anticompetitive harm that the purchasers are not alleging. The objections should be overruled. The purchasers did not abandon the theory of anticompetitive harm identified by *Actavis*, and the R&R correctly concludes that the purchasers had sufficient evidence for the jury to find that Merck paid Glenmark to avoid the competitive risk posed by Glenmark.[39]

1. The R&R is not based on a theory of anticompetitive harm that the purchasers abandoned.

The R&R observes "Plaintiffs' theory of anticompetitive harm as being that Defendants' settlement avoided the risk of competition because it avoided the risk of patent invalidation in the *Glenmark* litigation itself."[40] This is correct, because the purchasers allege, and have now shown by substantial evidence, that the Merck-Glenmark pact included a no-AG commitment by Merck along with an agreement by Glenmark to drop 100% of its imminent challenge to Merck's patent. (At the time, the trial of Glenmark's patent challenge was mere days away).

According to the defendants, this conclusion is wrong because "Plaintiffs have abandoned any theory that, but for the challenged provision, the Glenmark case would have proceeded to trial in 2010 and the patent would have been invalidated, as the R&R recognized."[41] This confuses liability with causation. The purchasers have consistently

[39] R&R at 47–48.

[40] Defs.' Objs. at 11–12.

[41] *Id.* at 12.

contended that Merck's no-AG commitment was exchanged for Glenmark's commitment to drop its patent challenge, and that absent a no-AG commitment, reasonable parties in the positions of Merck and Glenmark would have reached a settlement with an earlier agreed entry date. The defendants' argument to the contrary improperly confuses the purchasers' evidence of an antitrust violation with the benchmark that they have presented to establish that the violation caused them some injury.

"[T]he traditional rule of reason is a burden-shifting framework for analyzing an agreement's anticompetitive effects."[42] In *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.* ("*Lamictal*"),[43] the Third Circuit explained how that burden-shifting analysis applies to reverse payments. First, "to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition."[44] This does not involve explicit proof of an exchange as the defendants demand. Rather, the "likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[45] Second, "the burden then shifts to the defendant to show 'that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.'"[46] Finally, the plaintiff gets "the opportunity to rebut the defendant's

[42] R&R at 49.

[43] 791 F.3d 388 (3d Cir. 2015).

[44] *Id.* at 412 (citing *Actavis*, 570 U.S. at 154–55).

[45] *Id.* (citing *Actavis*, 570 U.S. at 159).

[46] *Id.* (quoting *Actavis*, 570 U.S. at 156).

explanation" of the payment.[47]

Nowhere in this rule-of-reason analysis is there any requirement to show when or how generic entry would have occurred absent the reverse payment. (In a private case for damages, that can be a requirement for causation or estimation of damages.) As to liability, the "relevant anticompetitive harm" of a reverse payment is that it "seeks to prevent the *risk* of competition."[48] The anticompetitive harm is not that the patent surely would have been invalidated if not for the settlement, but that "'a large and otherwise unjustified reverse payment was made as part of the settlement in order to shore up some perceived risk' of competition."[49]

AndroGel rejected the argument that proof of anticompetitive effects requires proof of an actual delay as inconsistent with *Actavis*:

> Rather than having to litigate the merits of any underlying patent suits or establish a theory of causation, the Supreme Court said that courts can look to the "size of the payment . . . [to] be able to assess its likely anticompetitive effects. . . ." Where the size of a reverse payment "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." But where a payment is "large and unjustified" by these traditional settlement concerns, it is likely directed toward avoiding the risk of competition. Thus, if the settlement payments are shown to be larger than what could reasonably be expected to cover such traditional settlement concerns as future litigation costs or the value of services rendered, the Plaintiffs will have satisfied

[47] *Id.*

[48] *Actavis*, 570 U.S. at 157 (emphasis added).

[49] *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016) (quoting *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 240 (D. Conn. 2015)); *see also In re AndroGel Antitrust Litig. (No. II*), No. 09-md-2084, 2018 WL 2984873, at *9 (N.D. Ga. June 14, 2018) ("[T]he Supreme Court made clear in Actavis that avoiding even the possibility of competition, however small, is itself an antitrust violation."); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *23 (D. Mass. Jan. 25, 2018) (requiring plaintiffs to prove "the but-for scenario in question actually occurred" to show an agreement is anticompetitive "is not and cannot be the standard").

> their burden in showing that the settlements violated the antitrust laws.[50]

The purchasers' election not to pursue a causation benchmark based on Glenmark's success in the patent litigation absent the defendants' no-AG agreement says nothing about whether the no-AG agreement was anticompetitive.[51] The question of causation arises only *after* the purchasers prove that the payment was anticompetitive.[52] The purchasers' theory of anticompetitive harm in this case has always been that the "relevant anticompetitive harm" of Merck's no-AG agreement was that it sought "to prevent the risk of competition" as established by the absence of any legitimate explanation for Merck's agreement.[53] The R&R correctly recognizes that the pendency of another lawsuit, the Mylan litigation, was not inconsistent with this position because, absent any contrary explanation of the no-AG agreement from the defendants, the payment permitted Merck to avoid the risk of competition from the lawsuit against Glenmark, even if Merck continued to face risk from the Mylan litigation.

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[50] *AndroGel*, 2018 WL 2984873, at *9 (quoting *Actavis*, 570 U.S. at 156, 158).

[51] *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2046f2 (4th ed. 2019) ("No-authorized-generic agreements . . . can in fact be more anticompetitive than a large cash payment for delay. . . . [A] no-authorized-generic provision compensates the generic with something far more troublesome [than a cash payment for delay]—namely, a second market division that serves to keep prices higher during the 180-day period when other generic firms are unable to enter the market.").

[52] *See, e.g.*, *AndroGel*, 2018 WL 2984873, at *17.

[53] *See, e.g.*, Purchasers' Opp'n at 2 ("Under *Actavis*, the 'relevant anticompetitive harm' of a reverse payment is that it 'seeks to prevent the risk of competition,' which plaintiffs can establish by proving a payment that exceeds the litigation expenses avoided by settling."); *id.* at 55 ("Under the rule of reason, the defendants are required to explain this large payment as something other than a payment to avoid the risk of the patent litigation and delay generic entry, but they simply deny that they entered into the Agreement that the evidence would permit a jury to find.").

2. The R&R correctly concludes that the purchasers' evidence is sufficient to support a conclusion that Merck paid Glenmark to avoid the risk of competition.

The R&R correctly rejects the defendants' argument that the purchasers did not have any evidence that Glenmark agreed to an entry date "in exchange" for the no-AG provision[54] because no explicit evidence of an exchange is necessary under *Actavis*, and because, even if it were, the purchasers had such evidence.

On the legal issue, the R&R recognizes, pursuant to *Actavis*, that a jury is permitted to infer from the size of a large and otherwise unjustified payment that the "payment's objective is to maintain supracompetitive prices to be shared. . . rather than face what might have been a competitive market."[55] The R&R follows the practice of some commentators in referring to this rationale as the *Actavis* inference and correctly points out that, "if Plaintiffs were required to produce explicit evidence of an unlawful agreement before invoking *Actavis*, there would be no need for an inference at all."[56]

The defendants make no additional effort to explain the no-AG provision as anything other than a payment to avoid the risk of competition. Instead, they point to their own witnesses' testimony that the no-AG agreement was not offered in exchange for the entry date in the settlement agreement. But, as the R&R concludes, the testimony of the defendants' negotiators was contradicted by their contemporaneous written documents and subsequent actions.[57] And even if not contradicted by the contemporaneous written record, the testimony was insufficient to establish the absence of material disputed facts given the defendants' failure to identify an

[54] Defs.' Objs. at 14.

[55] R&R at 51 (quoting *Actavis*, 570 U.S. at 157).

[56] *Id.* at 52.

[57] *Id.* at 54.

explanation for the no-AG provision to rebut the clear inference that Merck offered it to Glenmark to avoid the risk of competition.[58] Indeed the contemporaneous documents reflecting the negotiations demonstrate repeated attempts by Merck and Glenmark to negotiate both the entry date and the consideration that Merck would pay Glenmark.[59]

The defendants continue to insist that Dr. McGuire and Dr. Leffler conceded that there was no evidence that the no-AG agreement was offered in exchange for the entry date in the settlement agreement. The R&R considers this argument and the testimony the defendants cite and concludes that "all McGuire and Leffler testified was that they had not 'seen . . . the communication that indicated an exchange, an explicit exchange between the two' in this case."[60] Dr. McGuire testified that "the settlement agreement itself" was evidence of an exchange."[61] And, Dr. Leffler "explained that settlement discussions provide 'a collection of value,' which is 'like a quid pro quo'. . . ."[62] As a result, the R&R is correct to reject the defendants' attempted spin on the testimony of Dr. McGuire and Dr. Leffler and to conclude that their testimony "can reasonably support a jury's inference that the Agreement included a reverse payment and avoided the risk of competition."[63]

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[58] *Id.* (observing that the cited testimony was "insufficient *on summary judgment* to conclusively refute a link between the provisions").

[59] Purchasers' Opp'n at 39–42; R&R at 33–34.

[60] *Id.* (quoting Tr. of June 24, 2020 Dep. of Thomas G. McGuire at 109:1–3, ECF No. 1039-23 ("McGuire Dep.")) (citing Tr. of July 9, 2020 Dep. of Keith Leffler at 269:19–271:8, ECF No. 1082-20 ("Leffler Dep.")).

[61] McGuire Dep. at 93:13–16.

[62] R&R at 55 (quoting Leffler Dep. at 270:3–16).

[63] *Id.*

3. The R&R correctly rejects the argument that *Actavis* requires a reverse payment to eliminate the risk of competition from every would-be generic.

The R&R correctly rejected the defendants' argument that this case is unlike *Actavis* and other reverse payment cases because the reverse payment did not eliminate Merck's risk of competition because of Merck's patent was also being challenged by another generic company, Mylan.[64] The defendants' argument is nonsensical and conflicts with the results of almost every other reverse payment case.

In *Actavis* itself, the brand manufacturer, Solvay, separately sued two generic manufacturers, Actavis and Par, on the same patent and reached separate settlements that were each challenged as containing reverse payments.[65] If the defendants were correct that a reverse payment must eliminate all risk to have anticompetitive effects, the Supreme Court certainly would have said so since neither reverse payment alone was sufficient to eliminate the risk of competition from every would-be generic.[66] The Court only emphasized that "the payment (if otherwise unexplained) likely seeks to prevent the risk of competition."[67] Similarly, *Modafinil* involved four separate settlements with reverse payments by Cephalon to generic manufacturers who shared first filer exclusivity and had been sued on the same patent. If the defendants were

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[64] R&R at 56 ("[I]t is not necessary that the settlement close the door on *all* potential risk.").

[65] *Actavis*, 570 U.S. at 145.

[66] The *Actavis* dissent recognized that the majority's opinion was not premised on the elimination of all risk of patent invalidation. It specifically pointed out that there could be subsequent litigation challenges to the patent and that, under the majority's opinion, a reverse payment would violate the antitrust laws because it eliminated some risk of patent invalidation, even if the patent's validity were ultimately upheld in the subsequent litigation. *Actavis*, 570 U.S. at 172–73 (Roberts, J., dissenting) ("According to the majority, the first settlement would violate the antitrust laws even though the patent was ultimately declared valid, because that first settlement took away *some chance* that the patent would be invalidated in the first go around." (emphasis added)).

[67] *Id.* at 157.

correct, none of these reverse payments could be found to violate the antitrust laws because a reverse payment to one would not eliminate the risk of losing to the others.[68] And, in *Wellbutrin XL*, the court of appeals rejected the district court's conclusion that a brand manufacturer's payment to a generic manufacturer was not actionable under *Actavis* where the generic manufacturer only agreed not to introduce a generic during the pendency of an appeal, and the litigation was permitted to continue. In reasoning directly applicable to the defendants' argument, the Third Circuit concluded that, even though the agreements did not end the litigation (i.e., eliminate all risk of competition), "they nevertheless implicate the kinds of concerns articulated in *Actavis* by delaying the entry of 150 mg generic Wellbutrin XL and by delaying the entry of an authorized generic version of both 150 and 300 mg Wellbutrin XL."[69]

If the purchasers must show that a reverse payment eliminated all the risk of competition from every would-be generic, virtually no reverse payment case could survive summary judgment. Even an undisputed cash payment of hundreds of millions of dollars to a first generic filer would not eliminate the chance of competition from a second generic manufacturer because, under the Hatch-Waxman Act, a second generic manufacturer can cause the first to forfeit its exclusivity by obtaining a final judgment with respect to the brand's patents.[70] And many cases finding sufficient evidence that a reverse payment violated the antitrust laws have involved

[68] *See In re Modafinil Antitrust Litig.*, 837 F.3d 238, 266 (3d Cir. 2016) (holding that all four generic manufacturers could be jointly and severally liable for damages arising from separate reverse payment agreements, even if there were no overall conspiracy); *King Drug Co. of Florence, Inc.*, 88 F. Supp. 3d at 417 (denying summary judgment with respect to all four reverse payments because the evidence created a genuine dispute of material fact as to whether the reverse payments were large enough to induce the four generic defendants to stay off the market).

[69] *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 162 n.50 (3d Cir. 2017).

[70] 21 U.S.C. § 505(j)(5)(D)(i)(I)(bb).

acceleration or contingent launch provisions like those in the Glenmark settlement that would permit a generic manufacturer receiving the reverse payment to enter earlier in the event that a subsequent generic was able to enter earlier.[71] None of these cases suggest that the reverse payment should not be actionable because it did not eliminate all of the risk of generic competition from every would-be competitor.

Finally, contrary to the defendants' argument,[72] the R&R recognizes that the competitive harm of reverse payment agreements must be evaluated at the time of the reverse payment settlement.[73] It states: "Paying [generics] to stay out of the market for the purpose of avoiding the risk of competition is an antitrust harm, *regardless* of whether or not the patent is valid and infringed."[74] Consequently, "[t]he fact that Merck later defended a reissued version of the same patent may bear on the strength of the expert opinions underlying causation and damages, but it is not a bar to liability as Defendants allege."[75] The Fifth Circuit reached a similar conclusion in *Impax Laboratories, Inc. v. FTC*,[76] where it relied on the same authority cited in the R&R to reject a defendant's argument that a reverse payment agreement was not "anticompetitive in hindsight" because, after making a reverse payment to the first generic filer, the brand obtained

[71] *See Modafinil*, 837 F.3d at 245–46 (contingent launch provision); *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 47 (1st Cir. 2016) (contingent launch provisions); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 320–21 (D.R.I. 2019) (acceleration provisions).

[72] Defs.' Objs. at 17–18.

[73] R&R at 71.

[74] *Id.* at 72 (quoting *AndroGel*, 2018 WL 2984873, at *11).

[75] *Id.* at 72–73; *see also* Herbert Hovenkamp, et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 16.01[D] at 16–30 (3d ed. 2017) ("[T]he correct analysis for exclusion payment settlements is based on the ex ante assessment of the patent's validity, not on how the patent ultimately fares ex post in the courts.").

[76] 994 F.3d 484, 496 (5th Cir. 2021).

additional patents that it successfully asserted to block subsequent generic entrants. The R&R does not err in reaching the same conclusion with respect to the result in the *Mylan* litigation.

Merck's success in the subsequent *Mylan* litigation is not relevant to whether Merck's reverse payment permitted it to avoid the risk of competition from Glenmark. As Magistrate Judge Miller recognizes (and the defendants sometimes agree), the time for assessing the competitive effects of a reverse payment are at the time of the settlement agreement, and the outcome in the *Mylan* litigation was not known at that time.[77] Magistrate Judge Miller considered that the purchasers' patent expert, Dr. Hrubiec, thoroughly reviewed the record in the *Glenmark* case, and opined that reasonable and competent counsel would have advised the parties in May 2010 that Glenmark had a 65% to 75% chance of success at trial.[78] And the evidence shows that Merck used the delay that it purchased from Glenmark "to re-set its trial strategy" to improve its chance of success against Mylan: Merck sought reissuance of the patent and deleted the claims at the heart of the inventorship defense, overhauled its expert lineup by shuffling responsibility for the key inventorship defense from one expert to another as well as adding a third expert to the team, spent eighteen additional months preparing against different counsel and different opposing experts, and benefitted from developments in the law on inequitable conduct.[79] These changes required Mylan to take a dramatically different approach to its inventorship defense than Glenmark did by asserting not just that the patentee improperly withheld the correct inventorship for compounds 4E and 4F as Glenmark had contended, but also for the ezetimibe compounds, which neither Glenmark, nor the claimed inventor of compounds

[77] Defs.' Objs. at 17; R&R at 71.

[78] R&R at 17–18.

[79] *Id*. at 18–19, 56–58.

4E and 4F, had ever asserted.[80]

The defendants nonetheless insist that Mylan's defense was exactly the same as Glenmark's defense[81] and the differences between the two cases are inconsequential. But the R&R correctly recognizes that, even though there was no reason to evaluate the cases differently at the time of the Glenmark settlement, the *Mylan* case ultimately proceeded to trial under a much different record.[82] The result on that subsequently developed record has no bearing on whether Merck paid Glenmark to avoid the risk of competition in 2010.

C. The R&R correctly recognizes a genuine dispute of fact as to the purchasers' causation theory.

1. The R&R correctly declines to recommend granting summary judgment on causation theories the purchasers are not pursuing.

The R&R correctly recommends that this Court deny summary judgment on causation theories that Glenmark would launch after winning the patent litigation or at-risk.[83] Under Rule 56, a party may move for summary judgment on a claim or part of a claim.[84] A particular theory that could be used to show that a violation caused delay is not a claim or part of a claim. A particular theory is just one way of establishing causation. Because the purchasers *are* pursuing an alternate settlement theory to satisfy the causation element of their claims, summary judgment is inappropriate on causation. In similar circumstances, a court has found a summary judgment

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[80] *Id.* at 18 ("[T]his caused Mylan to take a different strategy than Glenmark, attempting to prove that Afonso was a co-inventor of ezetimibe as well as Compounds 4E/F.").

[81] *Id.* at 56–58.

[82] *Id.* at 57 ("Merck argues that Plaintiffs have conceded the absence of any objective evidence that Defendants would have evaluated the Mylan and Glenmark cases differently, and thus Merck must have 'understood itself to face the exact same risk in both cases.' This assertion ignores substantial evidence that the Mylan case proceeded to trial under a very different record." (quoting Merck's Reply at 22, ECF No. 1213)).

[83] Defs.' Objs. at 18–19.

[84] Fed. R. Civ. P. 56(a).

motion on an unpursued causation theory to be moot.[85] The purchasers will show at trial that it would have been economically profitable for rational, profit seeking companies in Merck's and Glenmark's positions to have agreed to an earlier entry date absent the illegal no-AG agreement. Because the purchasers' experts rely on objective evidence of Merck's and Glenmark's chances of success in the patent litigation in determining the alternative no-payment entry date, evidence about the chances of success in the patent litigation will be presented at trial. Magistrate Judge Miller is correct to recommend that the Court merely "clarify" that the purchasers are precluded at trial from pursuing these causation theories.[86]

2. The R&R correctly finds there is sufficient evidence of causation to withstand summary judgment.

The R&R properly rejects the defendants' arguments that (1) there is no evidence these particular defendants would have entered into an alternate settlement that did not include the illegal no-AG reverse payment and (2) the opinions of the purchasers' economists, Dr. McGuire and Dr. Leffler are a mere "possibility" and not the "probability" that is required to survive summary judgment.[87]

First, as Magistrate Judge Miller recognized in a related *Daubert* decision that this Court has already affirmed, the purchasers are not required to prove conclusively through direct evidence what *would have happened* absent the illegal anticompetitive conduct: "[t]he relevant question on antitrust causation is whether companies in Merck's and Glenmark's position would

[85] *See, e.g.*, *Solodyn*, 2018 WL 563144, at *13 (denying summary judgment on abandoned litigation success theory as moot). Contrary to the defendants' arguments, *Wellbutrin XL* did not grant summary judgment with respect to a causation theory that plaintiffs were not pursuing; it granted summary judgment on causation because it held that the plaintiffs did not have *any* viable causation theory. 868 F.3d at 167–70.

[86] R&R at 62.

[87] Defs.' Objs. at 19–20.

have agreed to an earlier entry date *without* the no-AG agreement, not whether they did not do so in the real world in the presence of the anticompetitive conduct alleged."[88] Upon proof of a violation, the burden of proving antitrust injury is "lightened" because "[t]he vagaries of the marketplace usually deny us sure knowledge of what plaintiff's situation would have been in the absence of the defendant's antitrust violation."[89] Plaintiffs "enjoy a considerable amount of leeway in 'constructing a hypothetical world free of the defendant['s] exclusionary activities[.]'"[90] Thus, contrary to the defendants' arguments, the purchasers are not required to show a "paper trail" from the actual world showing what the defendants would have done had they not violated the antitrust laws.[91] There is no requirement to show that Merck and Glenmark discussed an earlier entry date.[92]

Second, as the R&R also recognizes, courts in other reverse payment cases have repeatedly endorsed the use of economic models such as those of Dr. McGuire and Dr. Leffler to identify an alternative no-payment entry date.[93] In fact, the defendants do not challenge the

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[88] *See* Mem. Order on Pls.' Mot. to Exclude Portions of Proposed Test. of Mark Robbins at 20, ECF No. 1315 ("Robbins Order"), *aff'd*, Mem. Order, ECF No. 1369.

[89] *J. Truett Payne Co., Inc. v. Chrysler Motors Corp.*, 451 U.S. 557, 566, 568 (1981).

[90] *Univac Dental Co. v. Dentsply Int'l, Inc.*, No. 07-cv-493, 2010 WL 1816745, at *3 (M.D. Pa. Apr. 27, 2010) (alterations in original) (quoting *LePage's, Inc. v. 3M*, 324 F.3d 141, 166 (3d Cir. 2003)); *see also In re Glumetza Antitrust Litig.*, No. 19-cv-5822, 2020 WL 4732333, at *9 (N.D. Cal. Aug. 15, 2020) ("It remains difficult, scratch that, impossible to know what would have happened absent defendants' unlawful conduct because, assuming the class wins, the unlawful scheme itself deprived us of that information. Estimates are, therefore, the only way to replay the film without the violation.").

[91] *Solodyn*, 2018 WL 563144, at *21 ("[I]f . . . [the defendants] were acting unlawfully to eliminate competition throughout their settlement negotiations, then it is unreasonable to expect a paper trail signifying rational, lawful business choices.").

[92] *United Food & Commercial Workers Loc. 1776 v. Teikoku Pharma USA* ("*Lidoderm*"), 296 F. Supp. 3d 1142, 1167, 1190 (N.D. Cal. 2017).

[93] R&R at 62–63 (citing *AndroGel*, 2018 WL 2984873, at *17; *Lidoderm*, 296 F. Supp. 3d at 1163; *Solodyn*, 2018 WL 563144, at *23).

admissibility of the models of Dr. McGuire and Dr. Leffler in their objections: "As the defendants concede, economic modeling of the type McGuire and Leffler employ is frequently and reliably employed in antitrust cases which present the problem of analyzing a hypothetical but-for world unaffected by the anticompetitive conduct."[94]

Instead, the defendants again challenge Dr. McGuire's and Dr. Leffler's opinions for failing to credit the defendants' tortured view of the "facts" in this case. In related *Daubert* briefing, the defendants claim that this failure rendered the economic opinions of Dr. McGuire and Dr. Leffler speculative and unreliable. Magistrate Judge Miller correctly rejected those arguments.[95] The defendants' re-hashed argument that Dr. McGuire's and Dr. Leffler's economic opinions only establish a "mere possibility" is insufficient to withstand summary judgment and should be rejected for the same reason. The economic models of Dr. McGuire and Dr. Leffler have been uniformly endorsed by the courts and have been deemed sufficient evidence of causation to withstand motions for summary judgment.[96] The defendants' two cases, *Sakaria* and *Wellbutrin XL*, are not to the contrary.[97]

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[94] R&R at 64 (citing *Lidoderm*, 296 F. Supp. 3d at 1162).

[95] *See* McGuire & Leffler Order; *see also* Pls.' Resp. to Defs.' Objs. to Mem. Op. and Or., ECF No. 1710 (the "McGuire & Leffler Resp.").

[96] *See, e.g.*, *AndroGel*, 2018 WL 2984873, at *17; *Solodyn*, 2018 WL 563144 at *21–23; *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 172–74, 199–202 (S.D.N.Y. 2018); *Lidoderm*, 296 F. Supp. 3d at 1189–90.

[97] *Wellbutrin XL* is inapposite because plaintiffs in that case did present the kind of economic evidence provided here by Dr. McGuire and Dr. Leffler to support an alternative settlement theory. *See In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 757–58 (E.D. Pa. 2015). Here, the purchasers have precisely the kind of expert evidence that was missing in *Wellbutrin XL* and are not pursuing an at-risk entry benchmark of the kind that *Wellbutrin XL* rejected. The Third Circuit's affirmance in that case did not concern the evidence required for an alternate settlement theory to survive summary judgment. Defs.' Objs. at 20–21. Rather, the Third Circuit held insufficient speculation that a third-party patent holder that was not party to the reverse payment would, in the but-for world, license a blocking patent to the generic defendant, when it

Third, the defendants are wrong that "[a]ll the evidence . . . "directly contradicts" the purchasers' alternative no-payment entry date theory.[98] The allegedly contradictory evidence is that Merck never offered an entry date during the negotiations as early as the no-payment entry dates identified by Dr. McGuire and Dr. Leffler. But that is neither surprising nor evidence of error on the part of Magistrate Judge Miller. All the entry dates that Merck and Glenmark discussed contemplated that Merck would provide substantial compensation to Glenmark in some form. Indeed, the Court already affirmed one of Magistrate Judge Miller's *Daubert* orders that recognized that the dates proposed during Merck's and Glenmark's negotiations were always coupled with some form of payment and were not evidence of the date that they would have agreed absent any reverse payment.[99]

Fourth, the R&R correctly rejects the defendants' arguments that Dr. McGuire's and Dr. Leffler's economic opinions are insufficient to withstand summary judgment because they relied on the opinion of the purchasers' patent expert, Dr. Robert Hrubiec, that at the time of the

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did not in the actual world. *See* 868 F.3d at 166–67. In contrast, Merck and Glenmark settled in the actual world. The question in this case is what would that settlement look like if the alleged illegal no-AG payment were stripped out, which is precisely the question that the economic models of Dr. McGuire and Dr. Leffler answer. *Sakaria v. Trans World Airlines*, 8 F.3d 164 (4th Cir. 1993), is even further afield. In that case, the plaintiff's medical expert concluded that decedent's heart attack was caused by the defendants based solely on statements purportedly made by the decedent. *Id.* at 171–72. The court excluded the decedent's statements as inadmissible uncorroborated hearsay, rendering the expert's conclusion "effectively renounced." *Id.* at 172–73. Here, the economic models of Dr. McGuire and Dr. Leffler show that it would have been profitable for companies in the position of Merck and Glenmark to negotiate an earlier entry date absent an illegal reverse payment. That economic analysis goes far beyond suggesting a "mere possibility."

[98] Defs.' Objs. at 21–22.

[99] *See* Robbins Order at 16–21 (rejecting argument that, because the defendants only ever offered "modest" earlier entry, the plaintiffs' alternative entry dates were "entirely speculative and unsupported" given that the defendants' "modest" dates were always coupled with some form of payment).

settlement, reasonable counsel would have advised both Merck and Glenmark that Glenmark was 65-75% likely to succeed in the litigation.[100] This re-hashed *Daubert* attack should be rejected for the same reasons discussed in the purchasers' response to the defendants' appeal of the order denying the defendants' motion to exclude the opinions of Dr. McGuire and Dr. Leffler.[101] The R&R correctly rejects the defendants' argument that Dr. Hrubiec's opinion on Glenmark's chances of success was inconsistent with Merck's victory against Mylan years later.[102] The patent cases were not identical. Immediately upon settling with Glenmark, Merck set out to improve its chances in the *Mylan* litigation. By the time of the Mylan trial, it was a very different case than the *Glenmark* case that would have been tried in May 2010.[103]

Fifth, Magistrate Judge Miller correctly rejects the defendants' argument that Dr. McGuire and Dr. Leffler's opinions are insufficient at summary judgment because they "assume that Merck's settlement with Glenmark eliminated *all* risk to Merck of having its Zetia patent invalidated" and "applied zero discount to account for the Mylan risk."[104] As discussed in the McGuire and Leffler Response: Dr. McGuire and Dr. Leffler did not "assume" that Merck's settlement with Glenmark eliminated all risk. Both testified that the posited Mylan risk would have had no material impact on the alternative entry date calculation because it would affect both

[100] Defs.' Objs. at 22–25.

[101] *See* McGuire & Leffler Resp. at 18–21, 26–27.

[102] *See* R&R at 64 (incorporating prior decisions denying the defendants' motions to exclude the opinions offered by Drs. Hrubiec, McGuire, and Leffler); *see also* McGuire & Leffler Resp. at 4, 11–13 & n.52, 21. As the R&R finds, in reverse payment cases, courts typically permit an economist to rely on an opinion of a patent expert as to the chances of success in the patent litigation, and, Dr. McGuire and Dr. Leffler both separately used economic analysis to confirm the reasonableness of Dr. Hrubiec's opinion. *See id.* at 11 & n.52, 26–27.

[103] McGuire &Leffler Resp. at 21.

[104] Defs.' Objs. at 24.

the value of the litigation and the value of the settlement similarly and accordingly have no material impact on the overall conclusions reached.[105] The defendants' expert, Dr. Addanki, conducted no calculation or analysis showing otherwise.[106] And there is no record evidence that in May 2010 any of the parties actually viewed the Mylan case as posing any kind of a risk.[107]

3. The R&R correctly concludes that there is a material dispute about whether Glenmark had the manufacturing capacity to launch earlier.

The R&R correctly concludes that the purchasers' evidence as to Glenmark's ability to launch generic Zetia in November 2014 was sufficient.[108]

The purchasers' evidence included the expert opinion of Susan Marchetti, who has over 35 years of experience at brand and generic pharmaceutical companies working in supply chain operations, including on the launch of more than 60 generic products.[109] Based upon her experience and review of the record, Ms. Marchetti opined that Glenmark could have launched on November 15, 2014, or any time later. Magistrate Judge Miller concludes that Ms. Marchetti was qualified to offer this opinion,[110] and that her testimony was "sufficiently reliable to create a dispute of material fact on [the issue of Glenmark's ability to launch using MSN's active pharmaceutical ingredient ("API")]."[111]

The defendants do not now and did not previously "challenge Ms. Marchetti's experience

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[105] McGuire & Leffler Resp. at 18–19.

[106] *Id.* at 21–22.

[107] *Id.* at 20.

[108] R&R at 65.

[109] *Id.* at 67.

[110] *Id.* at 66–67 (citing the relevant standards for qualification of an expert by virtue of experience).

[111] *Id.* at 66.

in the relevant field" or file a *Daubert* motion to attack the factual basis of her opinion.[112] Rather, they argue that Ms. Marchetti did not have sufficient facts to support her conclusions as to MSN's ability to supply the API Glenmark would have needed to launch in November 2014. In particular, they take issue with Ms. Marchetti's use of information included in several 2013 Certificates of Analysis ("COAs") generated by MSN to support her conclusions about MSN's ability to provide Glenmark with sufficient API to launch in November 2014.

The defendants argue that Ms. Marchetti's opinion is speculative because she did not have knowledge about the operation of MSN Labs that they contend is needed to "reliably interpret MSN Labs' COAs to reach her conclusions regarding that company's capacity."[113] But as the R&R notes, "Marchetti also testified that she did not need this information to understand the data reflected on the MSN Lab's COA."[114] The defendants present no evidence to the contrary. While the defendants assert that Ms. Marchetti's analysis of MSN's COAs to determine MSN's API batch rate cannot possibly be used to support her conclusions, they have no expert of their own to so opine or otherwise interpret the COAs.[115] And, they have no evidence that contradicts Ms. Marchetti's conclusions based upon the COAs.[116] Instead, the defendants simply criticize Ms. Marchetti's opinion without "demonstrate[ing] as to some dispositive element of the claim that there is no dispute about a fact which would prevent the plaintiff from

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[112] *Id.* at 67; *see also* Hr'g Tr. at 53 and 59:6–8 ("the issue here is you're sort of attacking the factual basis. That was an issue addressed in other *Daubert* motions . . .[.]").

[113] *Id.* at 68 (summarizing Glenmark's argument); Defs.' Objs. at 26 (making the same argument).

[114] *Id*. at 68 (citing Tr. of June 29, 2020 Dep. of Susan Marchetti at 124:20–126:3, ECF No. 1039-27 ("Marchetti Dep.")).

[115] *See* Defs.' Objs. at 26.

[116] Hr'g Tr. at 60:22–24 ("[I]t doesn't sound like there is any contrary information. There are no contrary assumptions in the record.").

recovering."[117] The record shows that Ms. Marchetti understands that a COA represents, among other things, the demonstrated output of an API supplier[118] and that her expert conclusion does not depend on the details that the defendants insist (without support) she needs.[119] Contrary to the defendants' assertions, Ms. Marchetti's opinion is not speculative.[120] She properly utilizes her experience in interpreting the COAs *in conjunction with* emails reflecting that Glenmark began communicating with MSN in 2008[121] about sourcing the API and email correspondence between Glenmark and MSN in June 2015 substantiating MSN's ability to supply API on a schedule consistent with that reflected in the COAs.[122]

The defendants also argue that the R&R errs regarding the import of certain 2015 emails between Glenmark and MSN regarding MSN's ability to supply API.[123] They argue that the emails undermine Ms. Marchetti's conclusions because they demonstrate that MSN's ability to

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[117] Hr'g Tr. at 62:5–8.

[118] Marchetti Dep. at 126:2–12.

[119] *Id.* 127:21–128:1 ("Q: And you don't have any information about how many steps were involved in MSN's process to make those three batches is that right? A: That's irrelevant."); *see also id.* at 285:3–12.

[120] *See VS Techs., LLC v. Twitter, Inc.*, No. 11-43, 2011 WL 4744572, at *6–7 (E.D. Va. Oct. 5, 2011) (expert opinion applying experience to facts and explaining how experience led to opinion is not "mere speculation," but rather is properly for the jury to consider). Both cases cited by the defendants for the unremarkable proposition that expert opinion cannot be based on speculation are inapposite. As already discussed above, *Sakaria* merely involved the lack of support for an expert's opinion about the cause of a heart attack after the expert's only support was stricken as inadmissible hearsay. *Sakaria*, 8 F.3d at 172–173; *supra* note 97. The other, *Dash v. Mayweather*, 731 F.3d 303, 317 & n.9 (4th Cir. 2013), found the plaintiff's expert's opinion on valuation of a lost licensing fee to be too speculative because the expert failed to expressly conclude that the work at issue actually had a fair market value.

[121] *See* Purchasers' Opp'n at 31–32 (citing numerous internal Glenmark emails, emails between Glenmark and MSN, and Ms. Marchetti's Opening and Rebuttal Reports).

[122] *See* Marchetti Dep. at 280:16–281:7.

[123] Defs.' Objs. at 27.

manufacture a particular quantity of API varied over time.[124] The R&R correctly concludes that these emails supplied additional cross check evidence in support of Ms. Marchetti's conclusions about MSN's ability to produce API in the "But-For World."[125] As Magistrate Judge Miller observes, the fact demonstrated by the offer that MSN "could produce the API in 2015 at a rate equivalent to the 2013 COAs could allow a reasonable juror to find that MSN Labs was capable of such a production by November 2013, which is long before the date either expert identifies for early entry in their alternative settlement models of the But-For World."[126]

4. The purchasers have created a genuine question of fact on antitrust injury.

The defendants claim that Magistrate Judge Miller erred in finding evidence of antitrust injury because Merck's patent was upheld in the *Mylan* litigation and the "exclusion from the market of an undisputedly *infringing* product cannot serve as the basis for antitrust injury."[127] The R&R correctly recognizes "[t]his argument misapplies the theory of antitrust injury. . . ."[128]

Antitrust injury is "injury of the type that the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful."[129] The relevant anticompetitive

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[124] *Id.*

[125] R&R at 68–69.

[126] R&R at 69. At oral argument, when the defendants' counsel presented a slide with the email and claimed that Ms. Marchetti was cherry picking from the email, Magistrate Judge Miller asked if Ms. Marchetti was examined about her interpretation of it. The defendants' counsel responded that he did not recall. Hr'g Tr. at 66:17–18. In fact, the email was included within Marchetti deposition Exhibit 10. When questioned about it, Ms. Marchetti explained that she used the email because "this email …tells me that within a six-month period they could make 1500 Kilos." Marchetti Dep. at 286:14–287:11. This is exactly the point on which the R&R finds the emails probative.

[127] Defs.' Obj. at 28.

[128] R&R at 71.

[129] *Brunswick Corp. v. Pueblo Bowl-O–Mat, Inc.*, 429 U.S. 477, 489 (1977).

harm of reverse payments is that they "prevent the risk of competition."[130] The antitrust injury that flows from avoiding competition is "higher drug prices."[131] Thus, to prove antitrust injury in a reverse payment case, purchasers must prove that "they suffered an injury in the form of higher drug prices because of the delay in generic entry caused by the reverse payment settlements."[132] Antitrust injury is "closely linked" to the question of causation.[133] The causation theory on which purchasers rely to demonstrate that Merck's reverse payment caused them to pay higher drug prices is that Merck and Glenmark would have agreed to an earlier generic entry date had Merck not paid Glenmark to delay generic entry. Higher prices are classic antitrust injury.[134]

First, the defendants claim that the purchasers' theory of antitrust injury is that "Merck's settlement with Glenmark was not *procompetitive enough.*"[135] That is not purchasers' theory. The purchasers' legal theory is that Merck's large unexplained payment to Glenmark violated the antitrust laws by avoiding the risk of competition, and that the illegal reverse payment caused them to suffer overcharges compared to a legal settlement in which Merck and Glenmark negotiated a generic entry date in the absence of a reverse payment.

Second, the defendants assert that purchasers' causation theory does not establish antitrust injury because purchasers must show that any alternative generic launch "would have

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[130] *Actavis*, 570 U.S. at 157.

[131] *AndroGel*, 2018 WL 2984873, at *12.

[132] *Id.*

[133] R&R at 59 (quoting *Wellbutrin XL*, 133 F. Supp. 3d at 762).

[134] *In re Mid-Atl. Toyota Antitrust Litig.*, 560 F. Supp. 760, 785–86 (D. Md. 1983) (recognizing overcharges as "the quintessential 'antitrust injury.'"); *Namenda*, 331 F. Supp. 3d at 212 (describing overcharges as "the classic antitrust injury." (quoting *Savory Pie Guy, LLC v. Comtec Indus., Ltd.*, No. 14-cv-7527, 2016 WL 7471340, at *12 (S.D.N.Y. Dec. 28, 2016))); *Wash. Cty. Health Care Auth., Inc. v. Baxter Int'l Inc.*, 328 F. Supp. 3d 824, 845 (N.D. Ill. 2018) (describing "[p]aying higher prices" as "paradigmatic antitrust injury").

[135] Defs.' Objs. at 28.

been legal."[136] But the purchasers satisfy any such requirement. Under the alternative no-payment settlement, Glenmark would have been able to legally launch pursuant to a license identical to the one in its actual settlement agreement with Merck. The only difference is that the alternative generic entry date would be earlier without Merck's payment to delay generic entry.

Third, the defendants assert that the purchasers' causation theory does not establish antitrust injury because "there is no way that Plaintiffs can show that the Merck-Glenmark settlement delayed competition for an amount unjustified by the patent's strength" because "a judicial finding of the patent's strength demonstrates that *any early entry by a generic is procompetitive*."[137] But there is no legal requirement for purchasers to prove the delay to be "unjustified by the patent's strength." To establish an antitrust violation, purchasers need only demonstrate a large and unjustified payment under the rule of reason. They need not prove the patent merits because the patent "may or may not be valid, and may or may not be infringed at the time of the settlement."[138] And, the ultimate outcome in the *Mylan* litigation is irrelevant to the purchasers' causation theory because, as Magistrate Judge Miller recognized, the *Mylan* case that Merck ultimately tried was far different from the *Glenmark* case that Merck settled.[139] Any settlement between Merck and Glenmark would be based on the facts as of May 2010, not those that developed years later.[140]

IV. CONCLUSION

For the foregoing reasons, the defendants' objections should be overruled.

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[136] *Id.* (quoting *Wellbutrin XL*, 868 F.3d at 165).

[137] *Id*. at 29.

[138] *Actavis*, 570 U.S. at 147.

[139] R&R at 72.

[140] Defs.' Objs. at 29.

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Respectfully submitted,

/s/ William H. Monroe, Jr.

William H. Monroe, Jr. (VSB No. 27441)
Marc C. Greco (VSB No. 41496)
Kip A. Harbison (VSB No. 38648)
Michael A. Glasser (VSB No. 17651)
GLASSER AND GLASSER, P.L.C.
Crown Center, Suite 600
580 East Main Street
Norfolk, VA 23510
Telephone: (757) 625-6787
Facsimile: (757) 625-5959
bill@glasserlaw.com
marcg@glasserlaw.com
kip@glasserlaw.com
michael@glasserlaw.com

Local Counsel for Plaintiffs FWK Holdings, LLC, Rochester Drug Cooperative, Inc., Cesar Castillo, LLC, McKesson Corporation, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, H.D. Smith, LLC, Smith Medical Partners, LLC, Valley Wholesale Drug Company, LLC, Cardinal Health, Inc., The Harvard Drug Group, L.L.C., Cardinal Health P.R. 120, Inc., Meijer, Inc., Meijer Distribution, Inc., SUPERVALU, Inc., Wegmans Food Markets, Inc., KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc., and MLI RX, LLC, and Member of the Direct Purchaser Executive Committee

Thomas M. Sobol (*pro hac vice)*
Kristen A. Johnson (*pro hac vice)*
Hannah Schwarzschild (*pro hac vice*)
Erin C. Burns (*pro hac vice*)
Bradley J. Vettraino (*pro hac vice*)
Rachel Downey (*pro hac vice*)
HAGENS BERMAN SOBOL SHAPIRO LLP
One Faneuil Hall Square, 5th Floor
Boston, MA 02109
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
tom@hbsslaw.com

kristenj@hbsslaw.com
hannahs@hbsslaw.com
erinb@hbsslaw.com
bradleyv@hbsslaw.com
racheld@hbsslaw.com

Lead Counsel for the Direct Purchaser Plaintiffs and Counsel for Plaintiffs FWK Holdings, LLC, McKesson Corporation, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, H.D. Smith, LLC, Smith Medical Partners, LLC, Valley Wholesale Drug Company, LLC, Cardinal Health, Inc., The Harvard Drug Group, L.L.C., and Cardinal Health P.R. 120, Inc.

David F. Sorensen (*pro hac vice*)
Ellen T. Noteware (*pro hac vice*)
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Telephone: (215) 875-3000
Facsimile: (215) 875-4604
dsorensen@bm.net
enoteware@bm.net

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiffs Rochester Drug Cooperative, Inc., McKesson Corporation, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, H.D. Smith, LLC, Smith Medical Partners, LLC, Valley Wholesale Drug Company, LLC, Cardinal Health, Inc., The Harvard Drug Group, L.L.C., and Cardinal Health P.R. 120, Inc.

Joseph M. Vanek (*pro hac vice*)
David P. Germaine (*pro hac vice*)
John P. Bjork (*pro hac vice*)
Paul E. Slater (*pro hac vice*)
Matthew T. Slater (*pro hac vice*)
John Bjork (*pro hac vice*)
SPERLING & SLATER, P.C.
55 W. Monroe, Suite 3200

Peter R. Kohn (*pro hac vice*)
Joseph T. Lukens (*pro hac vice*)
FARUQI & FARUQI, LLP
One Penn Center, Suite 1550
1617 John F. Kennedy Boulevard
Philadelphia, PA 19103
Telephone: (215) 277-5770
Facsimile: (215) 277-5771
pkohn@faruqilaw.com
jlukens@faruqilaw.com

Bradley J. Demuth (*pro hac vice*)
FARUQI & FARUQI, LLP
685 Third Avenue, 26th Floor
New York, NY 10017
Telephone: (212) 983-9330
Facsimile: (212) 983-9331
bdemuth@faruqilaw.com

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiffs Rochester Drug Cooperative, Inc. and MLI RX, LLC

Michael L. Roberts (*pro hac vice*)
Karen Sharp Halbert (*pro hac vice*)
Stephanie Smith (*pro hac vice*)
Sarah E. DeLoach (*pro hac vice*)
ROBERTS LAW FIRM, P.A.

Chicago, IL 60603
Telephone: (312) 641-3200
Facsimile: (312)641-6492
jbjork@sperling-law.com
jvanek@sperling-law.com
dgermaine@sperling-law.com
jbjork@sperling-law.com
pes@sperling-law.com
mslater@sperling-law.com

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiffs FWK Holdings, LLC, Meijer, Inc., Meijer Distribution, Inc., and SUPERVALU, Inc.

Linda P. Nussbaum (*pro hac vice*)
Peter Moran (*pro hac vice*)
NUSSBAUM LAW GROUP, P.C.
1211 Avenue of the Americas, 40th Floor
New York, NY 10036-8718
Telephone: (917) 438-9189
lnussbaum@nussbaumpc.com
pmoran@nussbaumpc.com

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiffs Cesar Castillo, LLC and Wegmans Food Markets, Inc.

John D. Radice (*pro hac vice*)
April Lambert (*pro hac vice*)
Daniel Rubenstein (*pro hac vice*)
Kenneth Pickle (*pro hac vice*)
Luck Smith (*pro hac vice*)
RADICE LAW FIRM, P.C.
475 Wall Street
Princeton, NJ 08540
Telephone: (646) 245-8502
Facsimile: (609) 385-0745
jradice@radicelawfirm.com
alambert@radicelawfirm.com
drubenstein@radicelawfirm.com
kpickle@radicelawfirm.com
lsmith@radicelawfirm.com

Member of the Direct Purchaser Executive

20 Rahling Circle
Little Rock, AR 72223
Telephone: (501) 821-5575
Facsimile: (501) 821-4474
mikeroberts@robertslawfirm.us
karenhalbert@robertslawfirm.us
stephaniesmith@robertslawfirm.us
sarahdeloach@robertslawfirm.us

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiffs FWK Holdings, LLC and KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc.

Steve D. Shadowen (*pro hac vice*)
Matthew C. Weiner (*pro hac vice*)
Tina Miranda (*pro hac vice*)
HILLIARD & SHADOWEN LLP
1135 W. 6th Street, Suite 125
Austin, TX 78703
Telephone: (855) 344-3298
steve@hilliardshadowenlaw.com
matt@hilliardshadowenlaw.com
tmiranda@hilliardshadowenlaw.com

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiff FWK Holdings, LLC

Joseph H. Meltzer (*pro hac vice*)
Terence S. Ziegler (*pro hac vice*)
KESSLER TOPAZ MELTZER & CHECK LLP
280 King of Prussia Road
Radnor, PA 19087
Telephone: (610) 667-7706
Facsimile: (610) 667-7056
jmeltzer@ktmc.com
tziegler@ktmc.com

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiff FWK Holdings, LLC

Barry Taus (*pro hac vice*)
Archana Tamoshunas (*pro hac vice*)
Kevin Landau (*pro hac vice*)

Committee and Counsel for Plaintiff FWK Holdings, LLC

Sharon K Robertson (*pro hac vice*)
Donna M. Evans (*pro hac vice*)
COHEN MILSTEIN SELLERS & TOLL PLLC
88 Pine Street, 14th Floor
New York, NY 10005
Telephone: (212) 838-7797
Facsimile: (212) 838-7745
srobertson@cohenmilstein.com
devans@cohenmilstein.com

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiff FWK Holdings, LLC

TAUS, CEBULASH & LANDAU, LLP
123 William Street, Suite 1900A
New York, NY10038
Telephone: (646) 873-7654
btaus@tcllaw.com
atamoshunas@tcllaw.com
klandau@tcllaw.com

Member of the Direct Purchaser Executive Committee and Counsel for Plaintiff Rochester Drug Cooperative, Inc.

Jayne A. Goldstein (*pro hac vice*)
Miller Shah, LLP
1625 North Commerce Parkway, Ste. 320
Fort Lauderdale, FL 33326
Telephone: (954) 515-0123
Facsimile: (866) 300-7367
jagoldstein@millershah.com

Counsel for Plaintiff Cesar Castillo, LLC

/s/ James A. Cales III
James A. Cales III (VSB No. 41317)
Alan Brody Rashkind (VSB No. 12658)
FURNISS, DAVID, RASHKIND & SAUNDERS PC
6160 Kempsville Circle, Suite 341B
Norfolk, VA 23502
Telephone: (757) 461-7100
arashkind@furnissdavis.com
jcales@furnissdavis.com

Local Counsel for the End-Payor Class

Marvin A. Miller (*pro hac vice*)
Lori A. Fanning (*pro hac vice*)
MILLER LAW LLC
115 S. LaSalle Street, Suite 2910
Chicago, IL 60603
Telephone: (312) 332-3400
mmiller@millerlawllc.com
lfanning@millerlawllc.com

Michael M. Buchman (*pro hac vice*)
MOTLEY RICE LLC
777 Third Avenue, 27th Floor
New York, NY 10017
Telephone: (212) 577-0040
mbuchman@motleyrice.com

Co-Lead Counsel for the End-Payor Class

/s/ John F. Sawyer
John F. Sawyer (VA Bar No. 65902)
WOLCOTT RIVERS GATES
Convergence Center V
200 Bendix Road, Suite 300
Virginia Beach, VA 23452
Telephone: 757-554-0249
Facsimile: 757-497-7267
sawyer@wolriv.com

Local Counsel for Burlington Drug Company, Inc., Dakota Drug, Inc., J M Smith Corporation d/b/a Smith Drug Company, Louisiana Wholesale Drug Co., Inc., North Carolina Mutual Wholesale Drug Company, Prescription Supply, Inc., and Value Drug Company, Giant Eagle, Inc., and the Retailer Plaintiffs

Bruce E. Gerstein (*pro hac vice*)
Kimberly Hennings (*pro hac vice*)
David B. Rochelson (*pro hac vice*)
GARWIN GERSTEIN & FISHER LLP
88 Pine St., 10th Floor
New York, NY 10005
Telephone: (212) 395-0055
bgerstein@garwingerstein.com
khennings@garwingerstein.com
drochelson@garwingerstein.com

Susan Segura
David Raphael
SMITH SEGURA RAPHAEL & LEGER LLP
221 Ansley Blvd.
Alexandria, LA 71303
Telephone: (318) 445-4480
ssegura@ssrllp.com
draphael@ssrllp.com

Stuart E. Des Roches
ODOM & DES ROCHES LLC
650 Poydras Street, Suite 2020
New Orleans, LA 70130
Telephone: (504) 522-0077
stuart@odrlaw.com

Counsel for Burlington Drug Company, Inc., Dakota Drug, Inc., J M Smith Corporation d/b/a Smith Drug Company, Louisiana Wholesale Drug Co., Inc., North Carolina Mutual Wholesale Drug Company, Prescription Supply, Inc., and Value Drug Company

Scott E. Perwin (*pro hac vice*)
Lauren C. Ravkind (*pro hac vice*)
Anna T. Neill (*pro hac vice*)
KENNY NACHWALTER P.A.
Four Seasons Tower
1441 Brickell Avenue, Suite 1100
Miami, FL 33131

Barry L. Refsin (*pro hac vice*)
Eric L. Bloom (*pro hac vice*)
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER P.A.
One Logan Square, 27th Floor
Philadelphia, PA 19103
Telephone: (215) 568-6200

Telephone: (305) 373-1000
Facsimile: (305) 372-1861
sperwin@knpa.com
lravkind@knpa.com
aneill@knpa.com

Counsel for the Retailer Plaintiffs (No. 2:18-cv-266) and Giant Eagle, Inc.

brefsin@hangley.com
mkiley@hangley.com
ebloom@hangley.com

Counsel for the Retailer Plaintiffs (Nos. 2:18-cv-423 & 2:18-cv-439)

Bernard D. Marcus
Moira Cain-Mannix
Brian C. Hill
Erin Gibson Allen
MARCUS & SHAPIRA LLP
301 Grant Street
One Oxford Centre, 35th Floor
Pittsburgh, PA 15219-6401
Telephone: 412-471-3490
Facsimile: 412-391-8758
marcus@marcus-shapira.com
cain-mannix@marcus-shapira.com
hill@marcus-shapira.com
allen@marcus-shapira.com

Counsel for Giant Eagle, Inc.

CERTIFICATE OF SERVICE

I, William H. Monroe, Jr., certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: September 30, 2022

/s/ William H. Monroe, Jr.
William H. Monroe, Jr. (VSB No. 27441)